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By separate order, this case is referred to Magistrate Judge Wang for general pretrial. Judge Wang will address this motion, and any other matters regarding discovery. The post-discovery conference scheduled for July 30, 2021 is hereby adjourned *sine die*.

Honorable Ronnie Abrams
U.S. District Court, Southern District of New York
40 Foley Square, Room 2203
New York, NY 10007

SO ORDERED.



Hon, Ronnie Abrams

July 21, 2021

Re: *Kragulj v. Cortes, D.D.S., Galella, D.D.S., et al*, No. 1:20-cv-08390-RA;
Letter-Motion to resolve refusal to provide evidence of safety and efficacy

Dear Judge Abrams:

Pursuant to Local Civil Rule 37.2 and your Individual Practices, counsel for plaintiff requests a conference to resolve a dispute arising out of Defendant Steve Galella's July 16, 2021 Supplemental Response to Plaintiff's Request for Production of Documents, Request No. 23, ("RPD 23"). The undersigned counsel for plaintiff met and conferred telephonically with Alan Fumuso, counsel for defendant Galella, on July 19, 2021 at approximately 9:30 am, but was unable to resolve the dispute. Plaintiff now seeks to compel production of certain critical documents referenced by Dr. Galella in his Zoom deposition of July 7, 2021. These documents are encompassed by said RPD 23.

The heart of plaintiff's litigation claim is that a dental/orthodontic appliance known as an Anterior Growth Guidance Appliance ("AGGA") or "Osseo-Restore" appliance, is a dangerous, sham product. Defendant Galella, a general dentist who helped developed the device, claimed in his deposition that his product can achieve certain results:

Q. Sure, you've told us that the maxilla remodels in three dimensions, correct?

A. Yes.

Q. Using an Osseo-Restore Device, correct?

A. Yes.

Q. And one of those directions is sagittal, right? On the sagittal plane?

A. Yes. It's three-dimensional, all at the same time.

-Deposition (suspended) of Dr. Steve Galella, p. 82-83

Q. In fact, would you agree that you represented to dentists prior to January 2018 that as much as 8 to 10 millimeters, if not more, of advancement of the maxilla in the sagittal plane can be obtained through the use of an Osseo-Restore Device?

A. Under certain circumstances, yes.

Q. What circumstances?

A. The amount of deficiency. The amount of bone. The closeness of the anterior teeth to the facial cortical plate. The angulation of the teeth, et cetera. There's a lot of factors.

Q. It depends on the patient, in other words?

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A. That's what I just said.
--Deposition (suspended) of Dr. Steve Galella, p. 92

Plaintiff will produce expert testimony to the effect that Dr. Gallella's claims are contrary to science and generally accepted principles of physiology, and are actually impossible in regard to adults, or "non-growers". In fact, the device instead pushes teeth through the alveolar bone to which they are attached, which can cause severe damage. Plaintiff's use of the device caused her to sustain serious, permanent and life-altering injury.

Defendant admits that there are no clinical trials, nor any peer-reviewed literature, that support his claims about safety and efficacy.

Q. What clinical trials or studies exist to this date which demonstrate the safety or efficacy of the Osseo-Restore Appliance?
A. That's been published?
Q. Published -- let's start with published, yes.
A. Not to my knowledge.
--Deposition (suspended) of Dr. Steve Galella, p. 66

Q. Right. Is there any reviewed article that supports the statement that ControlledArch Osseo-Restore Growth Appliance System has been successfully utilized in clinical practice in regard to non-growers?
A. Not that I'm aware of.

--Deposition (suspended) of Dr. Steve Galella, p. 64

However, he testified that he does possess "proof" or "evidence" that AGGA does as he claims. More specifically:

Q. I believe you've told us that you've seen 5 to 6 as a norm average or normal amount and as much as 8 to 10 or more of millimeters of advancement of maxillas in the sagittal plane among other dimensions as a result of Osseo-Restore Device use, correct?
A. Yes.
Q. And you've told me, if I understood what you said, that you have objective evidence of same in the form of either x-rays, CBCTs, scans or films, correct?
A. Well, among other things. Clinical measurements, et cetera, yes.
--Deposition (suspended) of Dr. Steve Galella, p. 87

Q. Do you still have those cases? That is, the films or other documents upon which you relied on for proof of efficacy of the Osseo-Restore or Restoration Appliance before this newsletter came out.
A. Sure.

--Deposition (suspended) of Dr. Steve Galella, p. 99

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This proof or evidence had earlier been requested by plaintiff in discovery. RPD No. 23 sets forth as follows:

23. Please provide the complete documentary basis for your opinion or conclusion, reached prior to January 2, 2018¹, that:
 - (a) AGGA was safe and efficacious for use in patients or some patients;
 - ...
 - (c) AGGA causes or can cause the maxilla or part of the maxilla to move anteriorly in adult patients;

A curt objection to this request, with no documents produced, was served by counsel for defendant Galella on March 29, 2021. Plaintiff and defendant Galella, through counsel, agreed to revisit this request and objection after said defendant's deposition, which occurred on July 7, 2021. On July 16, 2021, said defendant supplemented his response by essentially: citing a lengthy list of articles (per Dr. Galella's deposition testimony above, none are "peer-reviewed"); referring to "the clinical response of many of the patients who have worn the AGGA appliance"; and stating, "Additionally, answers to the aforementioned question #23 can be found in the deposition testimony of DR. GALELLA." Unfortunately, however, Dr. Galella failed to produce the documentary proof or evidence of safety and efficacy that he clearly testified he maintains, and which was requested in RPD #23.

One would think that if Dr. Galella possessed radiographic and photographic evidence that his device works as claimed, he would want to show it to plaintiff and eventually to this Court and to a jury. His refusal to produce it speaks volumes. Instead, plaintiff submits, defendant Galella is well aware that an AGGA can no more make an adult maxilla advance 5 or more mm than any other device can cause an adult to grow 5 or more mm taller. It is time, plaintiff respectfully submits, for Dr. Galella to either produce the objective proof or evidence he claims he has to support his AGGA claims, or concede that there is no such proof.

Plaintiff accordingly requests that Dr. Galella be compelled to respond fully and completely to RPD 23(a) and (c) [for documents up to the present, per footnote 1], including producing the proof or evidence he described at deposition in the form of x-rays, scans or films, and clinical measurements taken of both models and patients, and which support his claims as to the safety and efficacy of the AGGA or Osseo-Restore device for adults.

Sincerely,

/s/ SEC

Scott E. Charnas

CERTIFICATE OF SERVICE

I hereby certify that this document will be sent this day, July 20, 2021, to counsel of record through the ECF system.

/SEC/

Scott E. Charnas

¹ A second Request for Production, served July 16, 2021 after Dr. Galella's deposition, expands the time frame for such requested documents to include up to the present time.